HPV Vaccination in India

Prof. (Dr.) Narendra K Arora
Executive Director
The INCLEN Trust International
nkarora@inclentrust.org

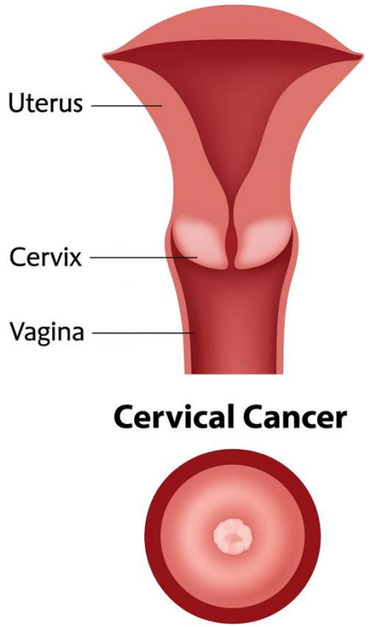
Cervical Cancer Burden in India

Cervical cancer stands as the **second leading cancer** amongst women in India, representing a critical public health challenge that demands urgent attention and comprehensive intervention strategies.

Alarming Statistics

- Estimated **79,103 new cases** and **34,805 deaths** annually (NCRP-ICMR, 2022)
- Approximately **one-fifth of new cases** globally
- Nearly **one-fourth of all deaths** from cervical cancer worldwide

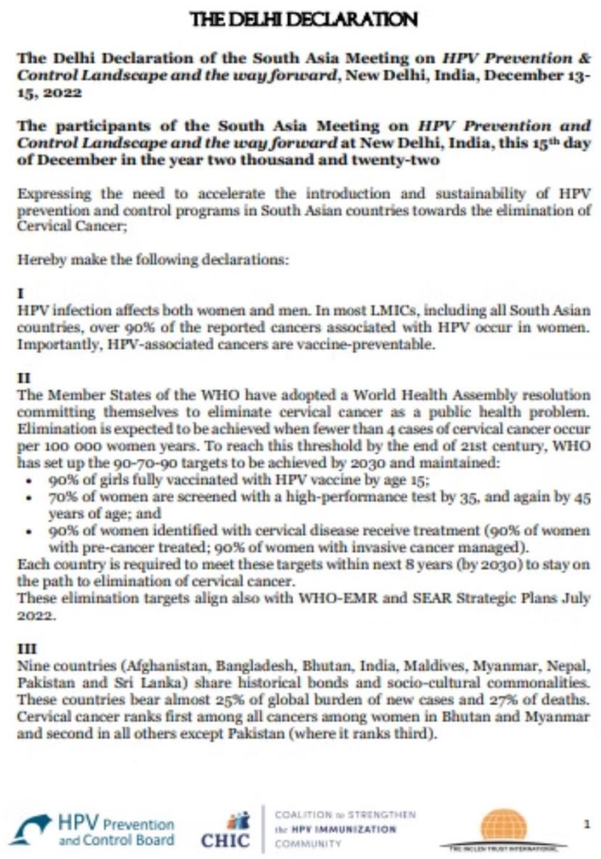
This disproportionate burden underscores the pressing need for effective prevention and control measures across the country.



Source: iarc.who.int

Delhi Declaration

South Asia Regional Meeting on HPV Prevention and Control



THE DELHI DECLARATION

The Delhi Declaration of the South Asia Meeting on *HPV Prevention & Control Landscape and the way forward*, New Delhi, India, December 13-15, 2022

The participants of the South Asia Meeting on *HPV Prevention and Control Landscape and the way forward* at New Delhi, India, this 15th day of December in the year two thousand and twenty-two

Expressing the need to accelerate the introduction and sustainability of HPV prevention and control programs in South Asian countries towards the elimination of Cervical Cancer;

Hereby make the following declarations:

I
HPV infection affects both women and men. In most LMICs, including all South Asian countries, over 90% of the reported cancers associated with HPV occur in women. Importantly, HPV-associated cancers are vaccine-preventable.

II
The Member States of the WHO have adopted a World Health Assembly resolution committing themselves to eliminate cervical cancer as a public health problem. Elimination is expected to be achieved when fewer than 4 cases of cervical cancer occur per 100 000 women years. To reach this threshold by the end of 21st century, WHO has set up the 90-70-90 targets to be achieved by 2030 and maintained:

- 90% of girls fully vaccinated with HPV vaccine by age 15;
- 70% of women are screened with a high-performance test by 35, and again by 45 years of age; and
- 90% of women identified with cervical disease receive treatment (90% of women with pre-cancer treated; 90% of women with invasive cancer managed).

Each country is required to meet these targets within next 8 years (by 2030) to stay on the path to elimination of cervical cancer.
These elimination targets align also with WHO-EMR and SEAR Strategic Plans July 2022.

III
Nine countries (Afghanistan, Bangladesh, Bhutan, India, Maldives, Myanmar, Nepal, Pakistan and Sri Lanka) share historical bonds and socio-cultural commonalities. These countries bear almost 25% of global burden of new cases and 27% of deaths. Cervical cancer ranks first among all cancers among women in Bhutan and Myanmar and second in all others except Pakistan (where it ranks third).

HPV Prevention and Control Board · CHIC · COALITION to STRENGTHEN the HPV IMMUNIZATION COMMUNITY · 1

The HPV Prevention and Control Board and the Coalition to Strengthen HPV Immunisation Community (CHIC), in collaboration with The INCLEN Trust International, convened a landmark regional meeting from **13th–15th December 2022** in New Delhi, India.

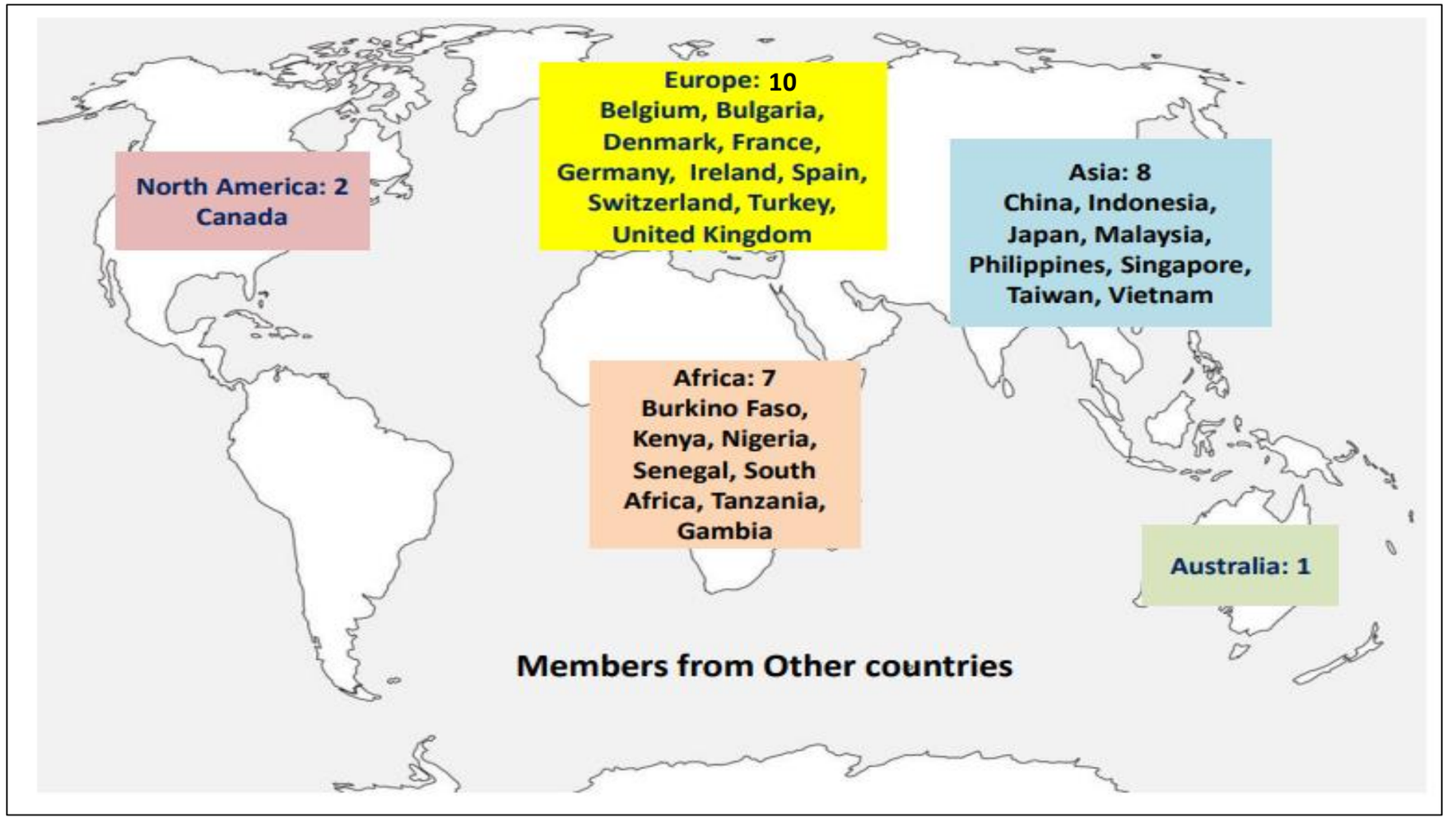
Key Objectives

To reinforce the introduction and sustainability of HPV prevention and control programmes in South Asia, participants endorsed the Delhi Declaration—a comprehensive commitment reflecting shared goals and full support of the global strategy to accelerate the elimination of cervical cancer.

The Declaration proposes concrete actions to reduce HPV-associated cancers through coordinated regional efforts, policy harmonisation, and enhanced programme implementation.

Source: uantwerpen.be/en/projects/hpv-prevention-and-control-board

Global Participation and Knowledge Sharing



233

South Asian Participants

Regional health professionals, policymakers, and program managers

28

International Participants

Experts from 10 countries worldwide

10

Countries Represented

Diverse perspectives from global health leaders

The meeting's global reach facilitated cross-regional learning, enabling South Asian nations to benefit from international best practices while contributing their own innovations and experiences to the worldwide experiences to the worldwide effort to eliminate cervical cancer.

Reference: www.uantwerpen.be/en/projects/hpv-prevention-and-control-board/meetings/southasia2022/

HPV Introduction

Building a Regional Network for Cervical Cancer Elimination

A landmark gathering bringing together public health leaders policymakers, and HPV program stakeholders from across South Asia t South Asia to advance cervical cancer prevention strategies an strengthen regional collaboration.

The South Asia Regional Meeting served as a critical platform for knowledge exchange, policy dialogue, and strategic planning. Participants engaged in comprehensive discussions on HPV vaccination implementation, screening programs, and treatment protocols tailored to the unique challenges facing South Asian populations. This collaborative approach strengthens regional capacity to combat cervical cancer through evidence-based interventions, shared resources, and coordinated advocacy efforts across national borders.

Total Participants from South Asian Region:

233 participants

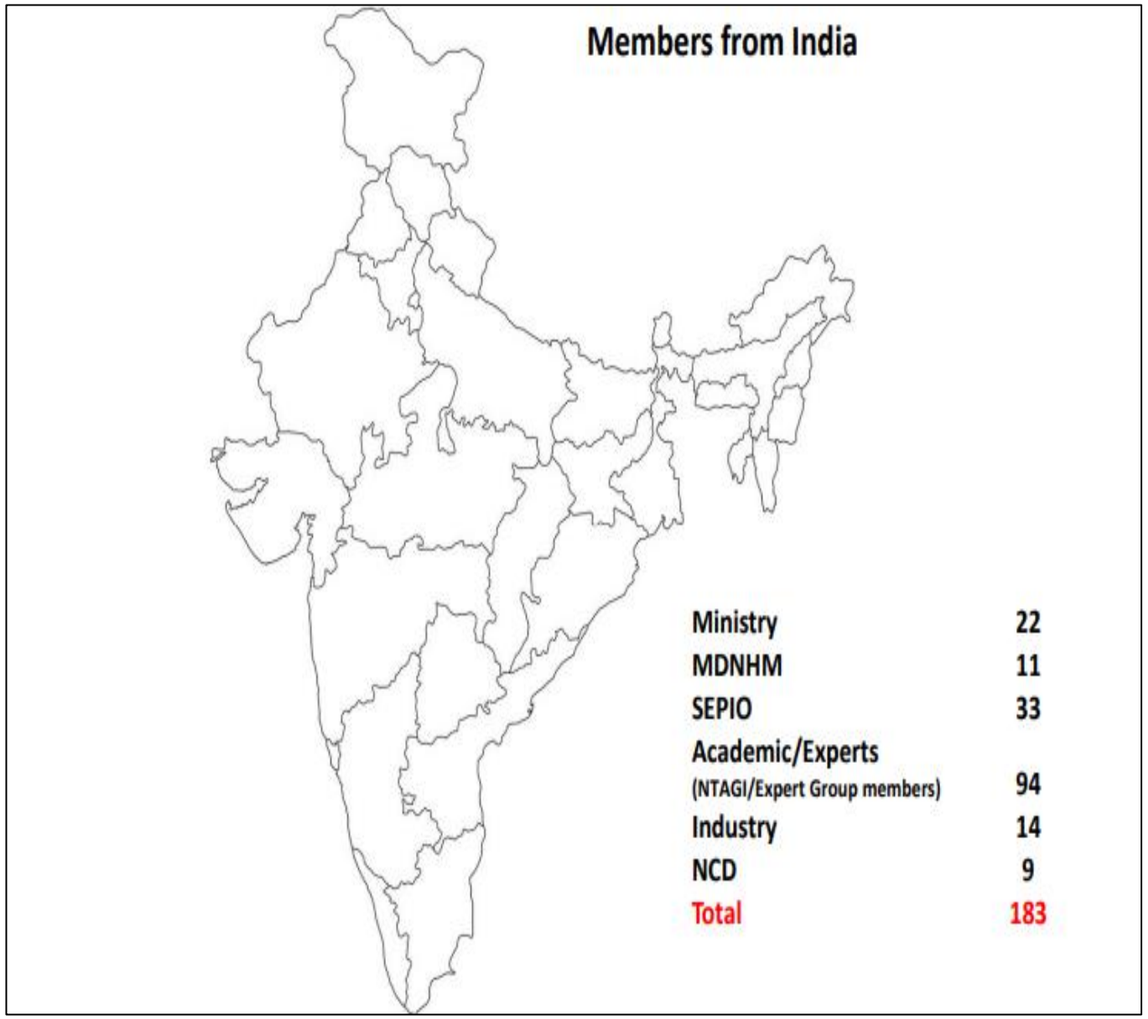
THE INCLEN TRUST

Indian Participation

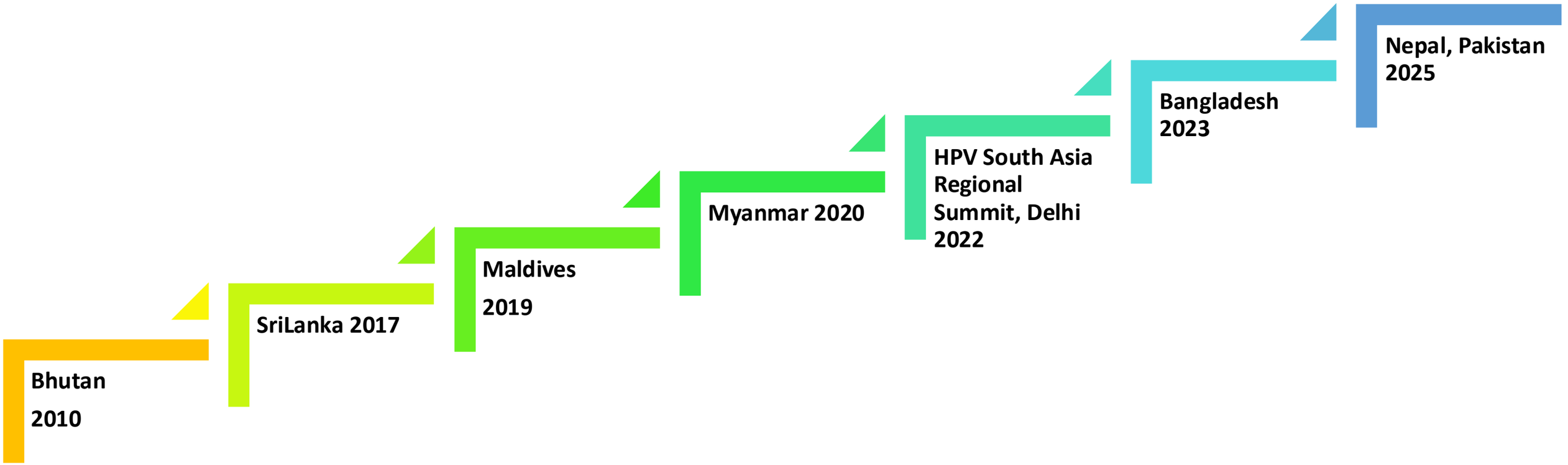
183 Participants from India

- Officials/members from
  - Ministry of Health and Family Welfare (MoHFW) and ICMR (n-22),
  - Mission Directorate–National Health Mission (MDNHM) (n-11),
  - State Expanded Programme on Immunization Officers (SEPIO) (n-33).
  - National Technical Advisory Group on Immunization (NTAGI) (n-8)
  - Non-communicable disease division (n-9)
- Academia (n-86)
- Industry sector (14 members)

Collectively, these members brought valuable insights and expertise to advance the regional agenda for cervical cancer elimination.



HPV Vaccine Introduction in South Asia Region



Yet to Launch: India, Afghanistan

Critical Challenges

Barriers to HPV Prevention and Control in South Asia

Accelerated Rollout

There is an urgent need to **accelerate** the rollout of vaccination programmes alongside comprehensive screening, diagnosis, and treatment facilities to create an integrated continuum of care.

Vaccine Delivery

Vaccine delivery systems must be acceptable, available, and affordable, addressing both supply-side constraints and demand-side barriers including cultural sensitivities and community awareness.

Screening Accessibility

Availability of **cervical screening** services in a culturally sensitive manner remains paramount, backed by appropriate linkages for timely diagnosis and effective management of cervical disease across all stages.

Treatment Quality

Scale and quality of **treatment for cervical cancer**, and its linkage with screening programmes across levels of health care, remain sub-optimal in all nine countries.

Data Gaps

Epidemiological data regarding HPV infection prevalence, genotype distribution, and cervical and other related cancers remain inconsistent and incomplete, hampering evidence-based planning.

Emerging Opportunities

Favourable Conditions for Programme Expansion

Political Commitment

Political will towards greater investment in cervical cancer elimination is strengthening, and the moment is opportune to harness this momentum across the South Asia region.

Production Capacity

By 2024, a significant increase in **global production capacity** of HPV vaccines is anticipated, resulting in a healthier and more competitive vaccine market with improved availability.

Vaccine Availability

Three **HPV vaccines** from large-volume manufacturers—one quadrivalent vaccine from India (CERVAVAC®) and two bivalent from China—are likely to become available soon, with several development efforts underway in India, Thailand, and other LMICs.

Single-Dose Schedule

The potential widespread adoption of a **single-dose schedule**, as recommended by WHO SAGE, shall lead to higher supply flexibility in the short term and significant programmatic advantages in the medium term.

NTAGI Recommendation for HPV Vaccination in India

In **June 2022**, India's National Technical Advisory Group on Immunisation (NTAGI) made a landmark recommendation for HPV vaccination implementation.

Recommended Strategy

- **One-time catch-up campaign** for girls aged 9–14 years (6-year multi-age cohort)
- Followed by **routine vaccination** at age 9 years
- Plan contingent on vaccine availability at affordable price

Current Implementation Challenges

- Existing global HPV vaccine manufacturers' supplies already committed to other markets
- Indian manufacturer SII's CERVAVAC® production currently below stated capacity
- Evidence under generation—ICMR study ongoing for single-dose efficacy

Source: mohfw.gov.in/sites/default/files/17th%20NTAGI%20Meeting%20Minutes

HPV Vaccination in India – Estimating Vaccine Volume Requirements

Understanding the scale of India's HPV vaccination initiative requires careful calculation of doses needed across different implementation scenarios. With an annual birth cohort of approximately 24 million girls and various rollout strategies under consideration, planners must balance coverage ambitions with supply realities.

Vaccine Volume Calculations: National vs. Phased Rollout

Full National Coverage

Using a two-dose schedule across India's entire population:

- **Single age cohort:** 24 million doses annually
- **Three age cohort catch-up:** 72 million doses (24M × 3)
- **Six age cohort catch-up:** 144 million doses (24M × 6)

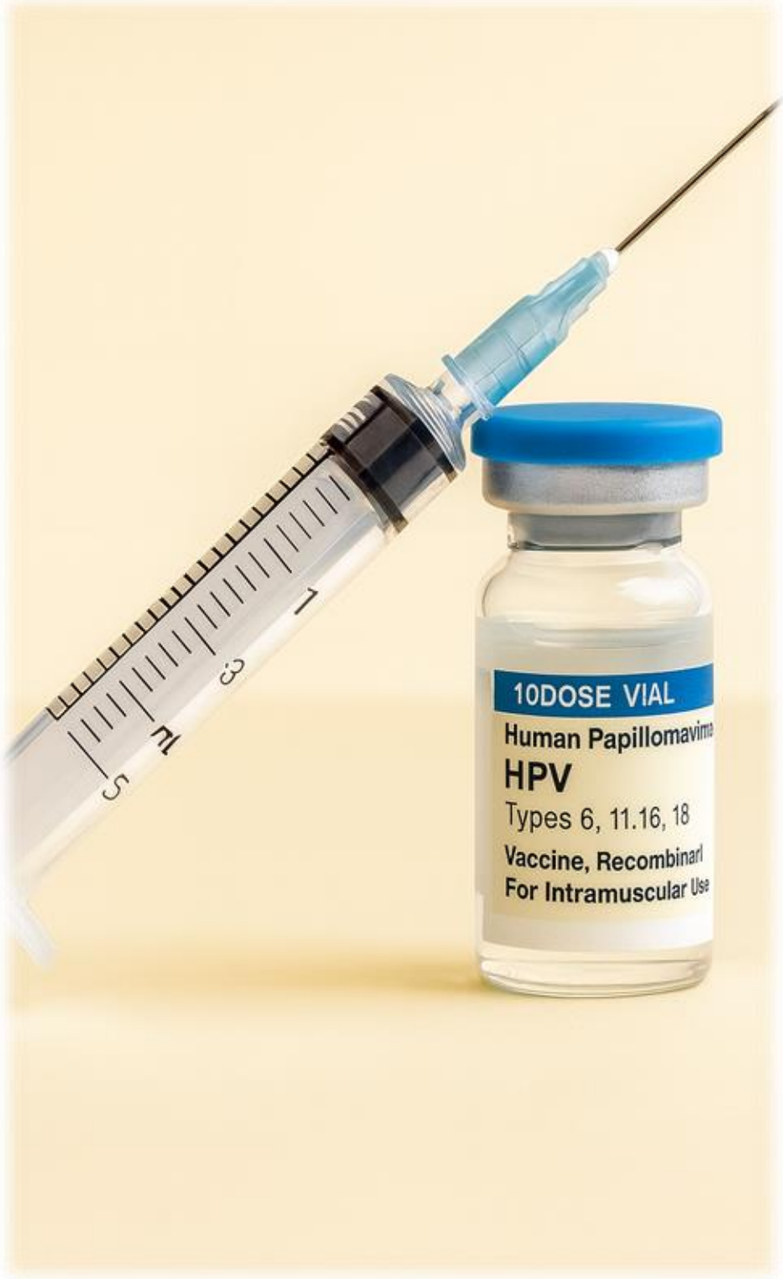
Based on 12 million girls per cohort requiring two doses each.

One-Third Country Approach

Government of India's proposed phased strategy:

- **Annual UIP requirement:** 8 million doses
- **Three cohort catch-up:** 24 million doses
- **Six cohort catch-up:** 48 million doses

This staged implementation reduces immediate supply pressure whilst building programme capacity.



Sources: *Journal of National Cancer Institute Monographs* / Draft Operational Guidelines – HPV Vaccine

Strategic Implementation Options for Two-Dose Schedules

Strategy One: Single Oldest Cohort

Target only 14-year-old girls with standard two-dose schedule, ensuring complete protection for the most immediately at-risk age group before expanding coverage.

Strategy Two: Limited Multi-Age Cohort

Begin with three age cohorts (12–14 years) using two-dose schedule, balancing broader initial coverage with manageable vaccine volumes and delivery infrastructure.

Strategy Three: Extended Interval Approach

Administer first dose to all 9-14-year-olds during 2025-2027, with second dose 3-5 years later only if ICMR study confirms necessity. WHO guidance supports intervals "up to 3 or 5 years" when programmatically beneficial.

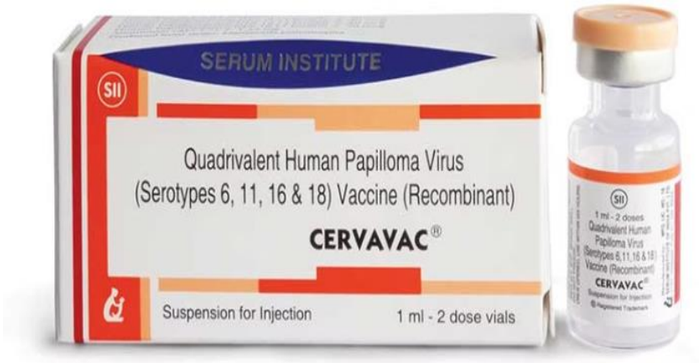
Key Challenge: Extended interval strategy requires robust e-immunisation platform to track first-dose recipients over 3-5 year period for second dose administration.

Impact of Early Introduction: These strategic approaches could prevent approximately 1.3-1.5 million lifetime cervical cancer cases in India.

Source: HPV World – Challenges in HPV Vaccine Introduction in India

Cervavac Single-Dose Immunobridging Study: Evidence for Future Scale-Up

The Indian Council of Medical Research (ICMR) launched a pivotal immunobridging study in December 2024 to evaluate whether single-dose Cervavac demonstrates non-inferiority compared to Gardasil. The study design adheres to WHO guidance for vaccine equivalence trials.



Potential Programme Impact

If successful, this study could transform India's vaccination strategy. A validated single-dose Cervavac would provide sufficient vaccine supply to cover **all eligible birth cohorts** nationally, dramatically expanding protection against HPV-related cancers.

Timeline: Study results are expected by late 2027, informing policy decisions on broader vaccine deployment and catch-up campaigns.

India's Single-Dose HPV Vaccine Strategy

India's Ministry of Health and Family Welfare (MOHFW) is implementing a groundbreaking single-dose HPV vaccination program, representing a transformative approach to cervical cancer prevention in one of the world's most populous nations.

Phased Launch Beginning December 2025

Gavi-supported rollout of **26 million doses** of **doses** of Gardasil (quadrivalent vaccine) across across 20 states, strategically selected based on based on high cervical cancer incidence rates rates and target population demographics. demographics.

Single-Age Cohort Strategy

Targeting girls aged **14 years** (those who have have celebrated their 14th birthday but not yet not yet their 15th) to maximize population coverage and prevent future age ineligibility ineligibility under program guidelines.

State Selection Criteria

- High cervical cancer incidence rates
- Target population size and accessibility accessibility
- Community willingness and acceptance
- School holiday scheduling considerations considerations

Campaign Approach: The vaccination program employs a focused campaign strategy rather than routine immunization, ensuring concentrated efforts to reach the target population efficiently during the initial rollout phases.

Source: Technical Document for Communication Working Group on HPV Vaccination, MOHFW India

Phase 1 & Phase 2: Operational Details

Geographic coverage - 20 priority states for initial HPV vaccine introduction across India.

Target Population

26 million adolescent girls in single age cohort (14 years)

Implementation Timeline

December 2025 through late 2027

Delivery Model

Health facility-based campaign in 20 states and union territories

Vaccine Specifications

Type: Virus-Like Particle technology | **Formulation:** Quadrivalent (HPV 6, 11, 16, 18) | **Brand:** Gardasil | **Schedule:** Single-dose regimen

Strategic Considerations

Phased geographic rollout enables operational learning, infrastructure strengthening, and evidence generation to inform subsequent phases and national scale-up strategies.

Gavi Partnership

26 million doses secured through Gavi, the Vaccine Alliance, demonstrating international commitment to cervical cancer elimination in low- and middle-income countries.

Source: Technical Document for Communication Working Group on HPV Vaccination, Ministry of Health and Family Welfare, Government of India

Three-Phase Implementation Roadmap

India's comprehensive HPV vaccination program will unfold in three strategic phases, progressively expanding coverage to protect millions of adolescent girls millions of adolescent girls against cervical cancer.

Phase 1: Foundation

Target: 12 million adolescent girls (⅓ cohort)

Vaccine: Gavi-supported 26 million single-dose Gardasil-4 across 20 priority states

Focus: Establishing delivery systems and community acceptance

1

Phase 2: Expansion

Target: 14 million adolescent girls

Vaccine: MOHFW-supported 40 million single-dose Cervavac-4 with domestic production

Focus: Geographic expansion and program refinement

2

Phase 3: Integration

Target: 40 million adolescent girls annually (1/3rd national cohort)

Vaccine: 8 million doses added yearly through Universal Immunization Program Program (UIP)

Focus: Sustainable routine immunization nationwide

3

This phased approach ensures systematic scale-up while maintaining program quality, enabling India to transition from campaign-based delivery to sustainable routine immunization integrated into the national health system.

Source: Technical Document for Communication Working Group on HPV Vaccination, MOHFW India

Thank you

F-1/5, Second Floor, Okhla Industrial Area, Phase-I, New Delhi - 110020

011-47730000

nkarora@inclentrust.org